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| APPLICATION NO.               | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/586,312                    | 04/16/2007  | Jukka T. Salonen     | 0933-0279PUS1       | 2435             |
| 2292                          | 7590        | 03/24/2008           |                     |                  |
| BIRCH STEWART KOLASCH & BIRCH |             |                      | EXAMINER            |                  |
| PO BOX 747                    |             |                      | HAMA, JOANNE        |                  |
| FALLS CHURCH, VA 22040-0747   |             |                      | ART UNIT            | PAPER NUMBER     |
|                               |             |                      | 1632                |                  |
|                               |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                               |             |                      | 03/24/2008          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/586,312             | SALONEN ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | JOANNE HAMA            | 1632                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 April 2007.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-39 and 41-64 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-39 and 41-64 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

This Application, filed April 16, 2007 is a 371 of PCT/FI05/50007, filed January 17, 2005, and claims priority to foreign Application 20040052, filed January 15, 2004, in Finland.

Applicant filed an amendment to the claims July 14, 2006. Claim 40 is cancelled. Claims 12, 19, 21-23, 34, 38, 39, 41, 46-48, 57, 58, 60, 61 are amended.

Claims 1-39, 41-60 are pending.

It is noted that claim 48 is missing a status identifier. Applicant is reminded that status identifiers must be indicated on amended claim sets or Applicant will risk non-entry of amendment, see 37 CFR 1.121.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-33, drawn to a method for detecting genetic variation of polymorphism in a defensin gene.

Group 2, claim(s) 34-39, 41, drawn to a method for treating a human or animal suffering from CHD or AMI.

Group 3, claim(s) 42-48, drawn to a kit for detecting genetic variation or polymorphism in a defensin gene for the determination of risk of acute myocardial infarction (AMI) and coronary heart disease (CHD) in a subject.

Group 4, claim(s) 49-58, drawn to an isolated variant nucleic acid encoding alfa-defensin-5 protein or beta-defensin-129 protein.

Group 5, claim(s) 59-61, drawn to a method for determining the presence or absence of a nucleic acid in a biological sample.

Group 6, claim(s) 62, drawn to a transgenic animal comprising a nucleotide sequence encoding a variant defensin nucleic acid.

Group 7, claim(s) 63, drawn to RNA interference methods involving a variant nucleotide sequence encoding a variant defensin nucleic acid.

Group 8, claim(s) 63, drawn to RNA interference models involving a variant nucleotide sequence encoding a variant defensin nucleic acid.

Group 9, claim(s) 64, drawn to a method for measuring defensin protein expression, production, or concentration in human tissue.

The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the following reasons: the special technical feature of the invention is detecting a genetic variation or polymorphism of a defensin gene. At the time of filing, the art teaches that detecting polymorphisms of the human beta-defensin-1 gene was known (see Dork and Stuhrmann, 1998, Molecular and Cellular Probes, 12: 171-173). Because the special technical feature was known at the time of filing, the claimed invention lacks unity.

The claims are further restricted.

Claim 39 of Group 2 is drawn to multiple treatments (dietary treatment, vaccination, or gene therapy/gene transfer) of treating a patient with CHD or AMI and one treatment must be elected. The multiple treatments lack unity of invention because while the “special technical feature” of treating by diet, is different from that of vaccination or gene therapy because the method requires different reagents and

methods. Similarly, vaccination requires different method steps from that of gene therapy/gene transfer.

Claims 49 and 50 of Group 4, claim 59 of Group 5, claim 62 of Group 6, claim 63 of Group 7 are drawn to a nucleic acid or use of a nucleic acid encoding a variant of alfa-defensin-5 protein or to a nucleic acid encoding a variant of beta-defensin-129 protein and a nucleic acid encoding a protein with a particular mutation or combination of mutations must be elected. The nucleic acids lack unity of invention because the “special technical feature” of the variant of alfa-defensin-5’s protein activity is different from that of the variant of beta-defensin-129’s.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 4, 5, 7 of Group 1 are drawn to various methods of detecting the presence or absence of a variant genotype of the defensin gene and one must be elected. The species lack unity of invention because the “special technical feature” of detecting presence or absence of a variant genotype is different amongst the techniques listed in claims 4, 5, 7.

Claims 13-15 of Group 1 are drawn to distinctly named mutations of particular genes and one must be elected. Further, claims 17, 18 of Group 1 are drawn to specifically named mutations of particular genes that further comprise the genetic variation that is to be detected and one or a specific combination of mutations must be

elected. The species lack unity of invention because the “special technical feature” of detecting one gene mutation is different amongst the various named genes and mutations.

Claim 37 of Group 2 is drawn to distinctly named defensins, as listed in claim 12, and one must be elected. The species lack unity of invention because the “special technical feature” of the patient comprising one of the defensins is different amongst the genes because each gene has a different biological activity.

Claim 43 of Group 3 is drawn to distinctly named defensins, as listed in claim 12, and one must be elected. Further, claim 45 of Group 3 is drawn to distinctly named mutations of particular genes that further comprise the genetic variation that is to be detected and one or a specific combination of mutations must be elected. The species lack unity of invention because the “special technical feature” of detecting one gene mutation is different amongst the various named genes and mutations.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic:

Claims 1-3, 6, 8-33 of Group 1 are generic for the various methods of detecting the presence or absence of a variant genotype of the defensin gene.

Claims 1-12, 16, 17, 19-33 of Group 1 are generic for the specifically named mutations in the defensin genes and for the genetic variations seen in alpha-2B-adrenoceptor, apolipoprotein B, and beta-2-adrenergic receptor.

Claims 34-37, 39, 41 of Group 2 are generic for defensins.

Claims 42-48 of Group 3 are generic for defensins.

Claims 42-48 of Group 3 are generic for the genetic variations seen in alpha-2B-adrenoceptor, apolipoprotein B, and beta-2-adrenergic receptor.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama, Ph.D./  
Examiner, Art Unit 1632